

§ 524.1044h

(i) From 7.5- or 15-g tubes; 10-, 12.5-, 15-, 25-, or 30-g bottles: 4 drops for dogs weighing less than 30 pounds (lb) or 8 drops for dogs weighing 30 lb or more.

(ii) From 20-, 40-, or 215-g bottles: 2 drops for dogs weighing less than 30 lb or 4 drops for dogs weighing 30 lb or more.

(ii) From 20- or 215-g bottles: 2 drops for dogs weighing less than 30 lb or 4 drops for dogs weighing 30 lb or more.

(2) *Indications for use.* For the treatment of acute and chronic canine otitis externa associated with yeast (*Malassezia pachydermatis*, formerly *Pityrosporum canis*) and/or bacteria susceptible to gentamicin.

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[58 FR 38973, July 21, 1993, as amended at 63 FR 31932, June 11, 1998; 68 FR 42970, July 21, 2003; 70 FR 8291, Feb. 18, 2005; 71 FR 13542, Mar. 16, 2006; 71 FR 16481, Apr. 3, 2006; 71 FR 38261, July 6, 2006; 71 FR 56867, Sept. 28, 2006; 78 FR 17597, Mar. 22, 2013; 79 FR 10969, Feb. 27, 2014]

§ 524.1044h Gentamicin, mometasone, and clotrimazole otic suspension.

(a) *Specifications.* Each gram contains gentamicin sulfate, United States Pharmacopeia (USP) equivalent to 3 milligram (mg) gentamicin base, mometasone furoate monohydrate equivalent to 1 mg mometasone, and 10 mg clotrimazole, USP.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—(1) Amount.* For dogs weighing less than 30 pounds (lb), instill 4 drops from the 7.5-, 15-, or 30-gram (g) bottle into the ear canal (2 drops from the 215-g bottle) or, for dogs weighing 30 lb or more, instill 8 drops from the 7.5-, 15-, or 30-g bottle into the ear canal (4 drops from the 215-g bottle), once or twice daily for 7 days.

(2) *Indications for use.* For the treatment of otitis externa caused by susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (*Pseudomonas* spp. [including *P. aeruginosa*], coagulase-positive staphylococci, *Enterococcus faecalis*, *Proteus mirabilis*, and beta-hemolytic streptococci).

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(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[66 FR 712, Jan. 4, 2001, as amended at 68 FR 15370, Mar. 31, 2003; 70 FR 36338, June 23, 2005; 79 FR 10969, Feb. 27, 2014]

§ 524.1044i Gentamicin and betamethasone ophthalmic solution.

(a) *Specifications.* Each milliliter (mL) of solution contains gentamicin sulfate equivalent to 3 milligrams (mg) of gentamicin base and 1 mg betamethasone acetate equivalent to 0.89 mg betamethasone alcohol.

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—(1) Amount.* Instill one or two drops of solution in the conjunctival sac three or four times a day.

(2) *Indications for use.* For treatment of external bacterial infections of the eye (conjunctiva and cornea).

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[75 FR 54492, Sept. 8, 2010]

§ 524.1132 Hydrocortisone, miconazole, and gentamicin otic suspension.

(a) *Specifications.* Each milliliter (mL) of suspension contains 1.11 milligrams (mg) of hydrocortisone aceponate, 15.1 mg of miconazole nitrate, and 1,505 micrograms of gentamicin sulfate.

(b) *Sponsor.* See No. 051311 in § 510.600(c) of this chapter.

(c) *Conditions of use in dogs—(1) Amount.* Instill 1.0 mL in the affected ear once daily for 5 days.

(2) *Indications for use.* For the treatment of otitis externa in dogs associated with susceptible strains of yeast (*Malassezia pachydermatis*) and bacteria (*Staphylococcus pseudintermedius*).

(3) *Limitations.* Federal law restricts this drug to use by or on the order of a licensed veterinarian.

[76 FR 78150, Dec. 16, 2011]

§ 524.1140 Imidacloprid and ivermectin.

(a) *Specifications.* The product is available in unit applicator tubes containing 0.4, 1.0, 2.5, or 4.0 milliliters (mL). Each mL of solution contains 100